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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

Applicant(s)

Inventor(s)

Attorney/Agent

Examiner

Art Unit

Thomas G. Larson, P.E.

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION

- Extensions of time may be available under the provisions of 37 C.F.R. 1.136(a) in no event, however, may a reply be filed more than SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. 35 U.S.C. 133.

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL** 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18, 23-27 and 29-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-18, 23-27 and 29-36 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d):
  - a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
    - 1. ☐ received.
    - 2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
    - 3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449, Paper No(s): \_\_\_\_\_)
- 18) ☐ Interview Summary (PTO-413, Paper No(s): \_\_\_\_\_)
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other \_\_\_\_\_

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-18, 23-27, and 36, drawn to pharmaceutical compositions comprising an inhibitor of osteonectin, and a method of tumor therapy comprising providing an inhibitor of osteonectin to a patient, classified in class 514, subclass 1, and to antisense molecules and vectors encoding the antisense molecules, classified in class 514 subclass 44, and/or class 536, subclasses 23.1 and 24.5.
  - II. Claims 29-31, drawn to a pharmaceutical composition comprising cells, or an extract of cells, transformed with a vector encoding an inhibitor of osteonectin, classified in class 424, subclass 520.
  - III. Claims 32 and 33, drawn to a pharmaceutical composition capable of stimulating a tumor cell to express IL-8 and method of using the cell in tumor therapy, classified in class 424, subclass 520.
  - IV. Claims 34 and 35, drawn to a pharmaceutical composition capable of stimulating a tumor cell to express GRO $\alpha$  and method of using the cell in tumor therapy, classified in class 424, subclass 520.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of group I (claims 10-17) can be practiced with a materially different composition such as the pharmaceutical composition of claims 1-9.

Inventions III and IV are distinct because each involves a composition for stimulating expression of a distinct cytokine (IL-8 vs. GRO $\alpha$ ) and a method of using that composition in tumor therapy.

The inventions of groups I and II are distinct from the inventions of groups III and IV because compositions materially different from inhibitors of osteonectin may be used to stimulate expression of the cytokines IL-8 and GRO $\alpha$ . Production of these cytokines is induced by a large number of stimuli including other cytokines, allergens, bacterial infection, and hypoxia.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

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matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The FAX numbers are (703) 308-4242 and (703) 308-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

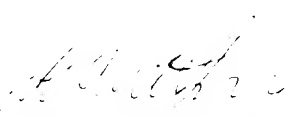
Unofficial papers, such as draft responses, may be transmitted to the examiner directly at (703) 305-7939. It is recommended that the examiner be notified when a fax is sent to this number.

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Any inquiry concerning this communication or earlier communications should be directed to Thom Larson, whose telephone number is (703) 308-7309. The examiner normally can be reached Monday through Friday from 9:00 AM to 5:30 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott, can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist, whose telephone number is (703) 308-0196.

Thomas G. Larson, Ph.D.  
Examiner

  
ROBERT A. SCHWARTZMAN  
PRIMARY EXAMINER